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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,818	07/24/2001	Daniel Pinkel	407E-914026US	8113

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,818

Applicant(s)

PINKEL ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-86 is/are pending in the application.
- 4a) Of the above claim(s) 47-55, 57, 62-67, 72, 73 and 77-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45, 46, 56, 58-61, 68-71 and 74-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the species about q22 to q24 of chromosome 17 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the election should be a Markush election. This is correct, and the form paragraph used was the Markush form paragraph. However, currently, no claim is completely generic. Every claim expressly limits the claim to sets of particular species. Also, it is noted that only claims 45, 46, 56, 58-61, 68-71, 74-76 will be examined. The remaining claims are non-elected.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

2. Claims 45, 46, 56 and 58-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,721,098 in view of Bloomfield et al (Cancer Res. (1983) 2975-2984).

Claims 1-27 of U.S. Patent No. 5,721,098 teach the method of comparative genomic hybridization for detection of chromosomal gains. The claims are generic to the use of the method on any DNA segment.

Bloomfield teaches that 17Q21-24 can be duplicated in large cell lymphomas (see page 2976, patient 44).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the comparative genomic hybridization(CGH) assay of claims 1-27 of U.S. Patent No. 5,721,098 with the disclosures of specific regions of interest of Bloomfield since an ordinary practitioner

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would have recognized that the method of comparative genomic hybridization could be used to identify any specific desired chromosomal abnormality and an ordinary practitioner would have also recognized that the CGH would have been useful as a diagnostic tool to characterize known chromosomal abnormalities. Since Bloomfield discloses the specific 17q22-24 region as of interest because of its duplication, an ordinary practitioner would have been motivated to use CGH to study amplifications in the 17q22-24 region.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 68-71 and 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alitalo (Proc. Natl. Acad. Sci. (1983) 80:1707-1711) in view of Hainsworth et al (Cancer Genet. Cytogenet. (1991) 53(2):205-18).

Alitalo teaches a method for detecting an amplification of 8q24 comprising contacting a chromosome sample with a labeled nucleic acid probe which binds to 8q24, detecting the hybridization complex and determining the copy number of the sequence (page 1708, subheading "c-myc is amplified in COLO 320 genomes").

Hainsworth teaches that, at least in some instances, there is chromosomal gain at 17q23 in primary breast cancers (see table 2, case 907, where there is a derivative of chromosome 17 which is translocated in 17q23, which represents an amplification at that position) .

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine amplification detection assays of Alitalo with the disclosures of specific regions of interest given by Hainsworth since an ordinary practitioner would have recognized that the extremely well known methods of southern blotting or in situ hybridization could be used to identify any specific desired chromosomal abnormality and an ordinary practitioner would have also recognized that the southern or in situ hybridization would have been useful as a diagnostic tool to

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characterize known chromosomal abnormalities. Since Hainsworth suggests the association of the 17q23 region with breast cancer, an ordinary practitioner would have been motivated to use either southern hybridization or in situ hybridization to diagnose the presence or absence of a specific region in order to correlate the phenotypic syndrome with that region. Finally, an ordinary practitioner would have recognized that the nucleic acid sources are well known in the art as equivalents, so that either cDNA or genomic DNA are well known targets for analysis.

Conclusion


7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1637

November 12, 2002